## REMARKS

### I. Status of the Claims

Claims 14-33 were pending. Claims 1-13 and 15-33 are cancelled. Applicants specifically reserve the right to pursue the non-elected subject matter or canceled claims in a divisional or continuing application. Claim 14 is amended. Claims 34 to 47 are newly added. Claims 14, and 34-47 are pending.

### II. Summary of Telephonic Interview

Applicants' representatives Charles Goyer, Michael Krawzsenek, and Charles Landrum ("Applicants") conducted a telephonic interview with Examiner Liu on March 20, 2007. The telephonic interview was in regard to the written description rejection of the phrase "compound" as used in claim 14. Applicants submitted to the Examiner that the decision of the United States Court of Appeals for the Federal Circuit in the case of *University of Rochester v. G.D. Searle* was not applicable to the current claim (358 F.3d 916, 920-923 (Fed. Cir. 2004). The Examiner concurred effectively removing the rejection. Applicants appreciate Examiner Liu's time and attention to this matter.

### III. Rejections Under 35 U.S.C. §112, First Paragraph

#### A. Claims 14-20, 22, 24, 25, 27, and 28 satisfy the written description requirement of 35 U.S.C. §112

Claims 14-20, 22, 24, 25, 27 and 28 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner proposes that the claims fail to complying with the written description requirement because (1) the specification allegedly fails to sufficiently describe the genus of SCN3A sodium channels; and (2) the specification allegedly fails to sufficiently describe the genus of test compounds. Applicants respectfully traverse.

Applicants have amended independent claim 14 to more precisely claim a SCN3A protein sequence. The amino acid sequence of SEQ ID NO:67 and nucleic acid sequence of SEQ ID NO:65 are disclosed in the specification and sequence listing as filed. The rejection of claim 14 based on a lack of written description for the genus of SCN3A sodium channels is moot.

Concerning the rejection based the lack of written description for the genus of test compounds, the Applicants respectfully disagree with the Examiner's position. Applicants submit that the basis for the Examiner's rejection is misplaced and the specification does provide written description for a method of selecting a compound that reduces the activity a SCN3A sodium channel. Applicants submit that having identified the SCN3A sodium channel as a channel associated with epilepsy, a person skilled in the art would readily understand that the SCN3A sequences claimed in claim 14 can be used in a number of screening assays to identify compounds (which could be totally unrelated in structure) that could modulate the activity of the SCN3A sodium channel. The claims are directed to methods of identifying a compound and thus, Applicants reiterate that the claim is not directed to the compounds themselves, but to the method of using a SCN3A to identify such. Of course, claim 14 being a screening claim, by definition, the method must include a step wherein the SCN3A activity associated with the claimed SCN3A sequences is compared in the presence versus in the absence of a test compound. Applicants submit that a skilled artisan now cognizant of the instant invention and of the disclosure could use the claimed assays without undue experimentation, particularly in light of the description on page 20 starting at line 20, page 21, page 47 starting at line 21, page 37 to 50, and from page 48, line 23 to page 49, line 22.

Applicants respectfully request the withdrawal of the written description rejections.

### B. Claims 14-20, 22, 24, 25, 27 and 28 satisfy the enablement requirement of 35 U.S.C. §112

Claims 14-20, 22, 24, 25, 27 and 28 have been further rejected under 35 U.S.C. §112, first paragraph because the specification purportedly does not enable a skilled artisan to make and use the invention commensurate in scope with these claims. In particular, the Examiner alleges that the claims fail to complying with the enablement requirement because the specification lacks an enabling disclosure for the use of a cell-free system.

In the interest of advancing prosecution in this case, the claims have been amended to no longer refer to cell-free systems. Applicants state that the cancellation of claim 27 should not be construed as an acknowledgement, admission, or disclaimer that cell-free systems are not enabled or that the present application lacks sufficient disclosure. Applicants reserve the right to pursue claims directed to cell-free systems for screening compounds that modulate SCN3A activity.

In view of the above and foregoing, the rejection of claims 14-20, 22, 24, 25, 27 and 28 under 35 U.S.C. §112, first paragraph is moot.

## IV. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 14-20, 22, 24, 25, 27 and 28 have been rejected under 35 U.S.C. §112, second paragraph as failing to particularly point out and distinctly claim the subject matter for which protection is sought.

Rejection of claims 14-20, 22, 24, 25 27 and 28 under 35 U.S.C. § 112, second paragraph is moot in view of the amendment to claim 14 which recites a "test compound" and cancellation of claim 16.

## V. Rejections Under 35 U.S.C. §102

Claims 14-20, 22, 24 and 28 have been rejected as being allegedly anticipated by Clare *et al.*, (Conference on Molecular and Functional Diversity of Ion Channels and Receptors, New York, NY May 14-17, 1998, published as Annals of the New York Academy of Sciences 1999, 868:80-83). Applicants respectfully traverse the rejection.

Applicants do not agree with the Examiner's allegation that Clare *et al.*, is a "Meeting Paper... held 14-17 May 1998". In any event, Clare *et al.*, allegedly discloses the cloning of a type III alpha subunit from human brain, a detection of a mRNA of approximately 9.5 kb in brain and heart tissues, as well as of a 7.5 kb fragment in skeletal muscle. The Applicants agree with the Examiner that Clare *et al.*, fails to disclose the sequence set forth in SEQ ID NO:65. The Examiner alleges SEQ ID NO:65 is an inherent property of the product. Applicants respectfully disagree and submit that for a reference to anticipate based on inherency the inherency must be **certain** (See, *e.g.*, *In re Oelrich*, 666 F. 2d 578, 581, 212 USPQ 323, 326 (CCPA 1981): *In re Oelrich* states:

> When an anticipation is based upon inherency, however, the inherency **must be certain**, i.e., the inherency may not be established by probabilities or possibilities. [emphasis added]

and *Ex parte Cyba*, 155 USPQ 757 stating:

> In order that a rejection based upon inherency may be sustained such inherency **must be certain**. [emphasis added]

The mere fact that the nucleic acid of the prior art has a similar size as the nucleic acid of the present invention (9.5kb as compared to 9.1kb, respectively), is clearly not sufficient in establishing that two nucleic acids are identical, and therefore that the sequence of SEQ ID NO:65 is an inherent property of the nucleic acid disclosed in the prior art. It is known that

sodium channels show high homology in several regions and it is therefore impossible to establish that the probe used by Clare *et al.* detects the nucleic acid of the present invention and not the nucleic acid of the alpha subunit of any other sodium channel (especially considering the fact that the sequence of the probe as well as the hybridization conditions used are not disclosed). Indeed, the detection of a 7.5kb band in skeletal muscle strongly suggest that the probe used by Clare *et al.*, is not specific to SCN3A, as SCN3A is not expressed in skeletal muscle (Thimmapaya R. *et al.* (2005), Eur. J. Neurosci., 22(1):1-9). In fact, it appears that the probe used by Clare *et al.* detects the nucleic acid encoding another sodium channel known as SCN4A, which is between 7.5kb and 8.0kb in size and is highly expressed in skeletal muscle (Wang *et al.*, 1992, Biochem. Biophys. Res. Commun., 182 (2), 794-801). Moreover, it is also well known that ion channels, such as voltage-gated sodium channels, have similar sizes. It is therefore inappropriate to solely rely on the size of the nucleic acid as evidence of identity to the nucleic acid of the present invention. Finally, Figure 1C of Clare *et al.* demonstrates that the $V_{1/2}$ (inactivation voltage) of the sodium channel identified and cloned is 58 mV, whereas the reported $V_{1/2}$ for SCN3A is 69 mV (Chen *et al.* (2000), Eur. J. Neurosci., 12 : 4281-4289), again suggesting that the nucleic acid disclosed by Clare is not SCN3A. Thus, Clare *et al.*, does not teach all elements of the claimed invention and therefore cannot anticipate the pending claims.

In view of the foregoing, and in particular, the above described evidence showing that inherency is clearly not "certain" based on Clare *et al.* Applicants respectfully request that the Examiner withdraw the rejection of claims 14-20, 22, 24 and 28 under 35 U.S.C. §102(b).

## CONCLUSION

Applicants believe that the present document is a full and complete response to the Action dated November 28, 2006. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Agent at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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